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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/523,455 | 03/10/00 | ENGEL | J PM 264671 |

HM12/0425
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EXAMINER

JIANG, S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 04/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/523,455

Applicant(s)

ENGEL ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

This application claims priority to two provisional applications Serial No. 60/127,241, 60/131,632.

Abstract

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objection

Claims 1, 5-12, and 16-19 are objected to for minor informalities. The employment of parenthetical expressions e.g., "(COS)" and "(ART)" in the claims 1 and 5-12 is considered informal. Further, the employment of a comma as a decimal expression, e.g., "0,5" in the claims 16-20 is considered informal.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2-4, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the start of a menstrual cycle... are programmed" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the programming of the start of a menstrual cycle " in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the intake of the last tablet " in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the

remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "assisted reproduction techniques" and the claim also recites "especially.." which is the narrower statement of the range/limitation. Claims 3 and 4 recite the broad recitation ""in the follicular phase" and the claim also recites "preferably.." which is the narrower statement of the range/limitation. Further, claim 22 recites "for example.." which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engel et al. (FR, PTO-1449 submitted September 27, 2000) and Albano et al. (PR, PTO-1449 submitted September 27, 2000) and Felberbaum et al. (RR, PTO-1449 submitted September 27, 2000) and Garfield (5,470,847, A, PTO-892) in view of Deghenghi (5,945,128, B, PTO-892) and Rabasseda et al. (U, PTO-892) and Kent (4,016,259 C, PTO-892).

Engel et al. discloses that an LHRH-antagonist, such as cetrorelix, is useful in the method of suppression of premature ovulation in controlled ovarian stimulation and assisted reproductive techniques, e.g., ICSI or intrauterine insemination by sperm injection, with multiple follicle and oocyte development. See the abstract, col. 1 lines 10-20, 30-34, 39-59, col. 2 lines 1-13, 16-25, col.3 lines 1-12, and claims 1-14. Engel et al. also discloses exogenous stimulation of the ovarian follicle growth and ovulation induction with HCG, LHRH, or LHRH-agonists and the stimulation is performed by administration of FSH or HMG with or without recombinant LH. See Abstract, col. 2 lines 38-43. Engel et al. further discloses the effective amount of the LHRH-antagonist cetrorelix within the instant claim to be administered during luteal phase. See Examples claim 6-8. Finally, Engel et al. teaches progesterone is useful in supporting the beginning of pregnancy. See col.1 lines 23-24.

Albano et al. teaches that LHRH-antagonists, such as cetrorelix, are useful in the method of suppression of premature ovulation in controlled ovarian stimulation and assisted reproductive techniques, e.g., IVF and ICSI, with multiple follicle and oocyte development, as well as the effective amount of the LHRH-antagonist cetrorelix within the instant claim to be administered during luteal phase. See Abstract, Introduction and Results. Albano et al. further teaches that progesterone concentration is significantly lowered due to the administration of cetrorelix. See page 2115, 5th paragraph of right column.

Felberbaum et al. teaches that LHRH-antagonists, such as cetrorelix and ganirelix, are useful in the method of suppression of premature ovulation in controlled

ovarian stimulation and assisted reproductive techniques, e.g., IVF and ICSI, with multiple follicle and oocyte development, as well as the effective amount of the LHRH-antagonist cetrorelix within the instant claim to be administered during luteal phase. See Abstract, page 399-402 Felberbaum et al. further teaches a fall of sex steroids due to the administration of LHRH-antagonists. See page 398, the last three lines.

Garfield teaches that the administration of progestogen in the follicular phase is useful along with other progestins, an estrogen, e.g. ethinylestradiol, and an LHRH-antagonist in a method of controlling ovarian stimulation and preventing conception. See abstract, col.1 lines 18-67 and col.5 lines 35-38. Garfield also teaches that the ovarian stimulation is achieved with antioestrogens, such as clomiphene, combined with gonadotropins. See col. 2 lines 9-17, col.5 lines 64-67 and col.6 lines 30-40.

The prior art does not expressly disclose that the particular LHRH-antagonist are teverelix, antide, and abarelix and their effective amounts to be administered. The prior art does also not expressly disclose that the ovarian stimulation therapy may be on Fridays to Mondays, and oocyte pick up and ART may be undertaken on Mondays to Thursdays. The prior art does not expressly further disclose the particular employment of oral contraceptive preparations containing progestogen and mestranol in the management of infertility.

Deghenghi discloses cetrorelix, teverelix, ganirelix and antide are known to be LHRH-antagonists. see col.2 lines 19-23.

Rabasseda et al. teach that LHRH-antagonists such as cetrorelix, ganirelix, and abarelix are known to be useful in the treatment of female infertility (see Introduction and Table 1 of page 397).

Kent discloses that the combination of progestogens and estrogen, i.e., mestranol and ethinylestradiol is useful in animal contraception (see col.1 lines 20-25).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular LHRH-antagonist such as teverelix, antide, and abarelix and to optimize their effective amounts to be administered, and to schedule or program the ovarian stimulation therapy on Fridays to Mondays and oocyte pick up and ART on Mondays to Thursdays, to employ the particular estrogen, mestranol, in oral contraceptive preparations along with progestogen.

One having ordinary skill in the art would have been motivated to employ the particular LHRH-antagonist such as teverelix, antide, and abarelix since teverelix, antide, and abarelix are known to be LHRH-antagonists, useful in the methods of controlled ovarian stimulation and assisted reproductive techniques and of the treatment of infertility according to Engel et al., Albano et al., Felberbaum et al., Deghenghi and Rabasseda et al. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan. One having ordinary skill in the art would have been motivated to schedule or program the ovarian stimulation therapy on Fridays to Mondays and oocyte pick up and ART on Mondays to Thursdays since scheduling or programming the

known ovarian stimulation therapy for Fridays to Mondays according to the calendar is considered well within the skill of artisan as the optimization of a result effective parameter, e.g., dosage regimen. One having ordinary skill in the art would have been further motivated to employ the particular estrogen, mestranol, in oral contraceptive preparations along with progestogen in the management of infertility since the known contraceptive preparations of Kent contain mestranol and progestogen, and estrogen and progestin containing contraceptive agents are known broadly to be useful in the therapeutic management of infertility. Since all method and composition components herein are known to be useful to treat or manage the infertility, it is considered prima facie obvious to combine them into a single method useful for the very same purpose. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

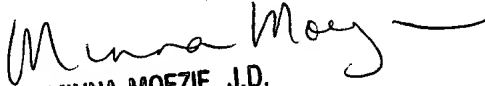
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 17, 2001


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